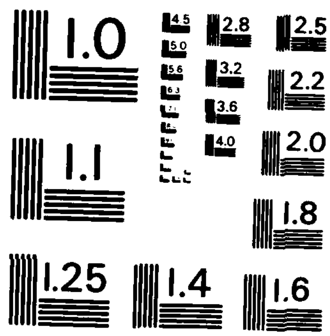
AD-A160 702   A PROPOSAL FOR A PREVALENCE STUDY OF THE USE OF ALCOHOL   1/1
AMONG WOMEN ATEEN..(U) AIR FORCE INST OF TECH
WRIGHT-PATTERSON AFB OH   H GILES JUN 85

UNCLASSIFIED   AFIT/CI/NR-85-124T   F/G 6/20   NL

END
FILMED
DTIC



MICROCOPY RESOLUTION TEST CHART
NATIONAL BUREAU OF STANDARDS-1963-A

UNCLASS

SECURITY CLASSIFICATION OF THIS PAGE (When Data Entered)

REPORT DOCUMENTATION PAGE

READ INSTRUCTIONS BEFORE COMPLETING FORM

1. REPORT NUMBER AFIT/CI/NR 85-124T	2. GOVT ACCESSION NO.	3. RECIPIENT'S CATALOG NUMBER
4. TITLE (and Subtitle) A Proposal For A Prevalence Study Of The Use Of Alcohol Among Women Attending Selected United States Air Force Prenatal Clinics		5. TYPE OF REPORT & PERIOD COVERED THESIS/~~DISSERTATION~~ 6. PERFORMING ORG. REPORT NUMBER
7. AUTHOR(s) Howard Gillis II		8. CONTRACT OR GRANT NUMBER(s)
9. PERFORMING ORGANIZATION NAME AND ADDRESS AFIT STUDENT AT: University of Texas Houston		10. PROGRAM ELEMENT, PROJECT, TASK AREA & WORK UNIT NUMBERS
11. CONTROLLING OFFICE NAME AND ADDRESS AFIT/NR WPAFB OH 45433 - 6583		12. REPORT DATE June 1985 13. NUMBER OF PAGES 55
14. MONITORING AGENCY NAME & ADDRESS(if different from Controlling Office)		15. SECURITY CLASS. (of this report) UNCLASS 15a. DECLASSIFICATION/DOWNGRADING SCHEDULE

16. DISTRIBUTION STATEMENT (of this Report)

APPROVED FOR PUBLIC RELEASE; DISTRIBUTION UNLIMITED

17. DISTRIBUTION STATEMENT (of the abstract entered in Block 20, if different from Report)

18. SUPPLEMENTARY NOTES

APPROVED FOR PUBLIC RELEASE: IAW AFR 190-1

Lynn Wolaver

LYNN E. WOLAVER
Dean for Research and
Professional Development
AFIT, Wright-Patterson AFB OH

18 Oct 85

19. KEY WORDS (Continue on reverse side if necessary and identify by block number)

20. ABSTRACT (Continue on reverse side if necessary and identify by block number)

ATTACHED

DTIC SELECTE OCT 30 1985 S D E

AD-A160 702

DTIC FILE COPY

DD FORM 1 JAN 73 1473 EDITION OF 1 NOV 65 IS OBSOLETE

UNCLASS

SECURITY CLASSIFICATION OF THIS PAGE (When Data Entered)

85 10 30 005

A PROPOSAL FOR A PREVALENCE STUDY OF THE USE OF ALCOHOL AMONG WOMEN ATTENDING SELECTED UNITED STATES AIR FORCE PRENATAL CLINICS

By

HOWARD GILLIS II, MD

APPROVED:

____

____

A PROPOSAL FOR A PREVALENCE STUDY OF THE USE OF ALCOHOL AMONG WOMEN ATTENDING SELECTED UNITED STATES AIR FORCE PRENATAL CLINICS

by

HOWARD GILLIS II, MD

PROJECT

Presented to the Faculty of the University of Texas

Health Science Center at Houston

School of Public Health

in Partial Fulfillment

of the Requirements

for the Degree of

MASTER OF PUBLIC HEALTH

THE UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER AT HOUSTON
SCHOOL OF PUBLIC HEALTH
Houston, Texas
June, 1985

ACKNOWLEDGEMENTS

I wish to express my sincere gratitude to the faculty for their invaluable assistance in the preparation of this project: first, to Dr Spurgeon H. Neel Jr., who encouraged me to pursue this topic; second, to Dr Alfonso H. Holguin, who provided experienced counsel; and finally, to Dr Clayton W. Eifler, who guided me through the statistical labyrinth.

Submitted 24 May 1985

A PROPOSAL FOR A PREVALENCE STUDY OF THE USE OF ALCOHOL AMONG WOMEN ATTENDING SELECTED UNITED STATES AIR FORCE PRENATAL CLINICS

Howard Gillis II, MD
The University of Texas
Health Science Center at Houston
School of Public Health, 1985

Supervising Professor: Dr Spurgeon H. Neel Jr.

The Fetal Alcohol Syndrome, caused by the exposure of the fetus to alcohol in utero, is now the number one teratogenic cause of mental retardation in the United States. Despite the danger that alcohol poses to the fetus, it's use by prenatal patients has not been well studied. The prevalence of the use of alcohol in women attending USAF prenatal clinics has never been reported, nor is there information on it's relation to cultural and economic factors. This study proposes to obtain the cooperation of selected USAF prenatal clinics where data on prenatal alcohol use will be collected by the use of a self-administered questionnaire. Alcohol use specific prevalence rates will be calculated, and the association of alcohol use to demographic factors will be measured using linear logistic regression.

TABLE OF CONTENTS

TABLE OF CONTENTS

Chapter 1

INTRODUCTION

In the United States, alcohol is the most widely used of all drugs (Lundberg, 1984). The United States Department of Health, Education and Welfare reported in 1975 that almost one-half of American women regularly use alcohol (Wilner, 1978). While there have been serious concerns since the earily 1960's about potential teratogenic effects of medications taken during pregnancy, concern about the effects of alcohol on the fetus is more recent (Ashley, 1981). It was not until 1980 that a *government report to the* President and Congress on the health hazards associated with alcohol consumption concluded that alcohol use during pregnancy could harm the fetus (Report..., 1980). The following year the United States Surgeon General issued an official advisory which warned women who were pregnant or considering pregnancy not to drink alcoholic beverages (FDA, 1981).

Despite this warning and the indications that alcohol use has been increasing among young women (Rosett, 1981), there are few recent studies of the prevalence of alcohol use among prenatal populations. Reported patterns of maternal alcohol use vary widely among the very few populations of pregnant women which have been studied (Streissguth, 1983). These wide variations and

the lack of knowledge about specific risk factors make it impossible to accurately estimate the prevalence of maternal alcohol use in unstudied groups.

LITERATURE REVIEW

DISCOVERY

The first known reference on the subject of maternal alcohol use during pregnancy appears in the Bible: Judges 13:7, when the Angel says to Sampson's mother,"... behold, you shall conceive and bear a son. Therefore beware and drink no wine or strong drink..." Both Carthage and Sparta had laws prohibiting the use of alcohol by newly married couples (Warner, 1975). Plato recommended the same rule, and Aristotle believed that drunken women often gave birth to abnormal children (Sokol, 1981). During the 18th century English gin epidemic, members of the Royal College of Physicians noted an increase in fetal wastage which they attributed to maternal intoxication (Ashley, 1981). The harmful effects of maternal drinking were explored extensively by medical researchers in the 19th and earily 20th centuries. Unfortunately, until recently those early studies have been discounted as unscientific and moralistic (Warner, 1975).

The first recent paper to identify an association between maternal alcohol use and fetal abnormalities was published in France in 1968 by Lemoine, et al., but attracted little attention. Working independently, Ulleland, et al., published similar findings

in 1970, but their data also went unnoticed. Then, in 1973, Jones, et al., published their findings of abnormalities similar to those described earlier by Lemoine and Ulleland in the children of eight alcoholic mothers. This third report finally alerted the modern medical community to the fact that chronic heavy use of alcohol by pregnant women is causally related with malformations and mental retardation in their children. The constellation of signs that Jones et al. described has become known as the Fetal Alcohol Syndrome (appendix 1).

Since that 1973 publication, additional adverse health effects on the fetus associated with more modest alcohol use have been described by other authors (Mills, 1984; Ouellette, 1984; Sokol, 1981). These adverse health effects are called Fetal Alcohol Effects (appendix 1) and have been associated with much lower levels of alcohol use than the Fetal Alcohol Syndrome (Ouellette, 1984). In one recent study, Mills, et al., (1984) reported a significant increase in the rate of intrauterine growth retardation in the children of women who consumed as little as one alcoholic drink daily.

In addition to the amount of alcohol a woman uses, the stage of pregnancy during which it is consumed is also important. Like most other teratogenic agents, exposure to alcohol in the first few weeks of pregnancy poses the greatest danger to the fetus (Rayburn, 1982). While chronic daily exposure to alcohol has proven harmful to the fetus, the effects of binge drinking remain unclear (Clarren, 1978). It is has been suggested that a single episode of intoxication in the first trimester, perhaps even before

the mother suspects she is pregnant, may adversely affect the fetus (Little, 1981).

COST

The Fetal Alcohol Syndrome is estimated to occur once in every 750 to 2000 births in the United States, affecting between 1650 and 4500 newborns each year (Segal, 1983; Little, 1981). While there are no reliable data on how many children are born with Fetal Alcohol Effects, their number is estimated to be many times greater than that of children with the full syndrome (Ouellette, 1984). Maternal alcohol use is now the most frequent known teratogenic cause of mental deficiency (Clarren, 1978) and produces the third most common syndrome associated with mental retardation (Ouellette, 1984).

Little (1981) estimated that New York State spends over $150 million each year to provide special care for children born with Fetal Alcohol Syndrome and alcohol related birth defects. Converting this to a national estimate yields an annual cost of between one and two billion dollars. This estimate does not include costs in human terms of the birth of these impaired children. These data are particularly unfortunate because fetal abnormalities due to alcohol are largely preventable.

PREVALENCE STUDIES

Previous studies of the prevalence of maternal alcohol use have produced remarkably different results. Significant variation

in drinking patterns has been found among different populations and even within the same population after women became aware of the danger of using alcohol during pregnancy. Rosett, et al., (1981) reported heavy drinking in 10%, moderate drinking in 40%, and rare drinking or abstinence in 50% of a group of 774 low socioeconomic pregnant women living in Boston who were surveyed from 1974 to 1977. In contrast, Mills, et al. (1984) studied 31,604 pregnant women attending a Kaiser-Permanente facility, also between 1974 and 1977, and found heavy drinking in only 0.5%, moderate drinking in 2%, and rare drinking or abstinence in 96%.

Streissguth (1983) reviewed 13 studies of maternal drinking published between 1973 and 1981 and found that reports of heavy alcohol use during pregnancy varied from 0.8 to 10.7%. Abstainers in those studies ranged from 19 to 58%. He attributed these differences to regional, cultural, and socioeconomic factors which actually influenced drinking habits, and to differences in methods of ascertainment.

SCREENING METHODS

Russel and Bigler (1979) have examined the question of the sensitivity and specificity of four different methods of identifying pregnant women with drinking problems. In a study of almost 500 patients they compared the sensitivity of a self-administered questionnaire, a series of questions by a physician during his examination of the patient, a blood alcohol test, and a review of the patient's medical record. To validate these screening tests, 68

randomly selected patients were subjected to a diagnostic consultation with an experienced alcohol counselor or consultant. Using the counselor's diagnosis as the standard of comparison, they found that the self-administered questionnaire had a sensitivity of 84% and a specificity of 94%. In comparison to the other screening methods the self-administered questionnaire was the most sensitive and approached the others in specificity.

Russel and Bigler's questionnaire consisted of 31 questions: eight on sociodemographic characteristics, one on smoking, twelve on alcohol use, and ten on alcohol-related problems. Women were asked how often they drank wine, beer, and liquor; and how often they had five or more drinks, three or four drinks, and one or two drinks of each beverage.

Rosett and Weiner (1981) condensed the drinking history to ten questions and incorporated it into the prenatal history. During a six month trial period they found that accounts of drinking patterns were recorded by clinic staff in 92% of the charts and were consistent with those obtained by research interviewers.

INTERVENTION

The reduction of the number of pregnancies in which the fetus is exposed to alcohol can be achieved through an effective intervention program. Streissguth, et al. (1983) reported the results of a community awareness program conducted over a six year period in Seattle, Washington. A media campaign, professional education, 24-hour hotline, and an open clinic for pregnant women

with alcohol problems were all used. The frequency of light, moderate, and heavy drinkers were each reduced by 50%, and the prevalence of women abstaining form alcohol during pregnancy doubled.

SURVEILLANCE

A maternal alcohol use surveillance system is a vital component of any prenatal care program. Information on trends in maternal alcohol use must be available in order to evaluate the effectiveness of any ongoing intervention, and to provide the basis for program modification to meet the changing needs of the community. Despite the importance of surveillance, there are no published reports on maternal alcohol use surveillance programs.

SUMMARY

The use of alcohol by pregnant women has been causally associated with significant congenital health problems which have implications for the practicing health professional, the health program planner and the policymaker. The responsibility for education regarding the danger which alcohol poses to the fetus and the identification and treatment of women who use alcohol during pregnancy lie with a wide range of health professionals. These include health educators, health care providers, and alcohol treatment specialists. The program planner must ensure that these professionals, functioning within the existing health care system, work together to provide effective preventive, diagnostic,

and treatment services to women who may become pregnant as well as those already pregnant. The policymaker should establish policies which provide an environment in which these programs can be conducted effectively.

STATEMENT OF THE PROBLEM

The danger that alcohol presents to the fetus makes it imperative that routine prenatal care includes effective surveillance and intervention programs to reduce or eliminate maternal alcohol use. Presently these services are not routinely offered at USAF Medical Treatment Facilities. In fact, there are no studies available on maternal drinking habits in USAF communities.

The absence of information regarding maternal drinking habits among active duty military women and dependent wives is a problem for the USAF physician. The use of results obtained from studies of civilian populations to estimate the prevalence of alcohol use in the USAF is unsatisfactory for two reasons. There is such wide variation in the prevalence reported that extrapolation of their results to other populations produces an uncertainty of at least an order of magnitude. In addition, there are significant social differences between USAF and civilian communities as well as among different USAF communities which may affect alcohol use.

In the absence of specific information on local maternal alcohol use, a Medical Treatment Facility's Health Education Coordinator has neither the objective basis to determine the need for a program to control prenatal alcohol use, nor a method to evaluate the effectiveness of any on-going efforts.

OBJECTIVES OF THE STUDY

This study will determine the prevalence of maternal alcohol use among women attending USAF prenatal clinics at selected Medical Treatment Facilities. In addition to estimating prevalence of maternal alcohol use in different clinics, the associations of eight demographic variables and maternal alcohol use will be investigated. Variables which are related to alcohol use will be used to construct a model which can identify women at greatest risk of alcohol use during pregnancy. The results will be given to the Health Education Coordinator at each of the Medical Treatment Facilities included in the study. Using these findings the Education Coordinator can plan and implement maternal alcohol use prevention, intervention and surveillance programs designed to meet the specific needs of the local prenatal population.

Chapter 2

METHODS

OVERVIEW

The study will be conducted in five phases. In the first phase, approval for the study will be obtained from the appropriate administrative sources. The second phase will encompass the final design, production, and distribution of all necessary printed materials. Phase three, data collection, will take place over three consecutive months. The analysis of that data will constitute the fourth phase. During the last phase, a final report of the results will be written, distributed to participating facilities, and submitted for publication. A detailed breakdown of the time required for each phase is presented in appendix 2.

DETAILS OF PROCESSION

APPROVAL

The approving authority for clinical studies conducted in USAF Medical Treatment Facilities is the Clinical Investigation Division of the USAF Medical Service Center (AFMSC/SGP). After

AFMSC/SGP approval has been obtained, the Commanders of all Medical Treatment Facilities selected to participate in the study will be contacted to obtain their support for the project. Facilities will not be included unless the Commander agrees to provide personnel to assist in data collection.

MATERIALS

Questionnaire

The questionnaire (appendix 3) will be divided into two sections. The first section will elicit demographic information. The name of the medical facility will be entered by the investigator before the questionnaire is sent to the study clinic. The patient will be asked to provide her age, ethnic group, military status, her (or her husband's) rank, and number of living children. She will also be asked whether she lives on or off the base, and whether she finished high school. These demographic factors will be independent variables.

The second part will deal with the drinking history. There will be questions on the type of alcohol consumed (beer, wine, or spirits), the amount, and the frequency of each type. The patient will also be asked if she has increased or decreased her use of alcohol over the past year. The prenatal use of alcohol will be the dependent variable.

Information and Consent Forms

An information form which explains the purpose of the study will be provided to each patient (appendix 4). The form also states that participation in the study is voluntary and that all responses will be strictly confidential. The consent form (appendix 5) specifies that the patient's responses may only be used for statistical purposes, that the responses will be kept confidential, and that the patient's name may not be used in any way.

DATA COLLECTION

Population

All new prenatal patients presenting for care at selected medical treatment facilities during a consecutive three month study period will be included. Patients previously receiving care at other bases who are relocated to a base which has a participating clinic will not be included. No prenatal clinic will be entered in the study which averages less than 20 new registrations per month to ensure that at least 60 subjects are available at each facility. An attempt will be made to include prenatal clinics in the study which differ in size, location (overseas or CONUS), and type (out-patient facility or hospital based).

Questionnaire Administration

Demographic and alcohol use information will be collected using a self-administered questionnaire which will be given to prenatal patients when they first register for prenatal care. The questionnaire will be included as part of the package of administrative materials that is completed by the patient when she registers as a new patient. The patient information sheet and consent form will be attached to the questionnaire.

A medical technician is always assigned to help patients complete their registration paperwork, and will be available to help them with the questionnaire. The technician will ensure that each patient reads and understands the patient information sheet, and that she signs the consent form prior to questionnaire completion. Instructions for technicians which explain how to obtain informed consent, assist with questionnaire completion, and care for the completed forms until returned to the investigator will be included in the package of materials sent to each prenatal clinic participating in the study.

Data will be collected simultaneously at the various Medical Treatment Facilities to eliminate the possibility of differences in drinking habits among clinics due to temporal factors (such as holiday periods).

Confidentiality

To ensure confidentiality, no personal identification will be entered on the questionnaire. The consent form, which will have personal identification, will be on a separate sheet of paper and will be attached to the questionnaire. Once the questionnaire and consent form are completed, they will be separated by the patient, placed in individual sealed envelopes, and returned to the technician. The sealed envelopes will be kept in a locked file until they are returned to the investigator.

Each questionnaire will have a code number which will be duplicated on the consent form. When the investigator receives the study materials, the patient's consent will be verified by matching the code numbers. After verification, the consent forms will be maintained in a locked file.

DATA ANALYSIS

Initial Stratification

Maternal drinking will be categorized as follows:

1. Nondrinkers - - - - - no reported alcohol use
2. Rare drinkers - - - - less than one drink daily
3. Light drinkers - - - - one to two drinks daily
4. Moderate drinkers - - three to five drinks daily
5. Heavy drinkers - - - - more than five drinks daily

A drink is defined as one can of beer, one glass of wine or one hard drink. The average daily number of drinks reported will be used to determine each patient's drinking category.

Prevalence Calculations

The percentage of patients in each of the five drinking categories will be calculated. Alcohol use specific prevalence rates will be calculated for each participating prenatal clinic. Prevalence rates will also be calculated using data pooled from all clinics participating in the study. Within each drinking category the percentage of patients reporting increased, decreased, or no change in drinking in the past year will be determined. Results will be displayed as histograms, one for each clinic and one for the pooled data (see appendix 6).

Secondary Stratification

After completing the prevalence calculation for each prenatal clinic the pooled data will be further analyzed in an attempt to fit a predictive mathematical model to that data. The model will permit the calculation of the odds that an individual drinks when she is characterized by any combination of eight binary demographic variables.

To produce this model, drinking categories one and two will be collapsed into a "non-drinking" group, "D-", and categories three,

four, and five combined to form the "alcohol use" group, "D+". The rationale for conversion to a binary variable is that while simplifying calculations, it does not detract from the desired results. Since all previously reported studies of maternal alcohol use have failed to show adverse fetal effects at average consumption rates of less than one drink daily, maternal drinking can be considered dichotomous with patients in the "D+" group at risk of producing affected children and those in the "D-" group free of increased risk.

The patients will be stratified according to each of the following variables:

variable	strata
1. Geographic location - - - -	(CONUS, overseas)
2. Patient age - - - - - - - - -	(<25, ≥25)
3. Socioeconomic Status- - -	(officer, enlisted)
4. Ethnicity - - - - - - - - - -	(white, non-white)
5. Military status - - - - - - -	(active duty, dependent)
6. Educational level - - - - - -	(<12th grade, ≥12th grade)
7. Domicile - - - - - - - - - - -	(on-base, off-base)
8. Parity - - - - - - - - - - - -	(0, >0)

The patient distribution between strata will be determined for each of the eight independent variables. As an example, for the variable "geographic location" the number of patients in the overseas and CONUS groups will each be counted. These data will be plotted as

histograms. Each of the strata will be divided again by drinking history and the data will then be tabulated (appendix 6).

Statistical Methods

CHI-SQUARE ANALYSIS

For each variable, a chi-square test of homogenity will be used to determine whether observed differences in proportions of drinkers between strata are significant. For comparing the two proportions, a chi-square statistic, "χ^2", with one degree of freedom shown below will be used.

$$\chi^2 = \frac{t\,(ad - bc)^2}{r \cdot s \cdot m \cdot n}$$

Where:

Variable

	group 0	group 1	
D+	a	b	r
D-	c	d	s
	m	n	t

The use of this statistic is appropriate because data is categorical and can be exhibited in 2x2 table format. It yields a measure of the association of the variable with drinking, but without controlling for other variables.

"P" VALUES

A "p" value will be calculated for each chi-square statistic. The "p" value is a measure of the probability that the differences in alcohol use that have been observed between the strata being compared could have occurred by chance alone. For the purposes of this study, "p" values less than .01 will be considered "significant." Thus, a comparison between strata which results in a "p" value of less than .01 suggests that the variable is related to alcohol use. For example, in the case of the variable "Domicile", if "p" is less than .01 it is likely that there is a difference in the prevalence of prenatal alcohol use between the stratum of patients who live on and those who live off the base. Chi-square statistics and their associated "p" values will be displayed as shown in appendix 7.

LINEAR LOGISTIC REGRESSION

Discussion of the Logistic Function

The pooled data will be used to generate a logistic function which expresses the natural log of the odds, called the "logit," that

a particular patient will be in the alcohol use group. The logit function is:

$$\text{logit } P(\mathbf{x}) = \ln \left\{P(\mathbf{x})/ 1-P(\mathbf{x})\right\}$$

where $\mathbf{x}$ is a vector quantity representing a set of independent variables $[x_1, x_2, \ldots x_n]$.

The initial model which will be used assumes that the logit is a linear function of all eight independent variables $(x_1, x_2 \ldots x_8)$ without interaction among any of the variables. Each of the eight binary variables, $x_1, x_2, \ldots x_8$, can assume the value of 0 or 1, according to the classification shown in appendix 8. With eight *binary variables*, $2^8 = 256$ *possible sets of patients are possible*. In terms of the independent variables, the logistic function is:

$$\text{logit } P(\mathbf{x}) = \alpha + \sum \boldsymbol{\beta}'\mathbf{x}$$

where $\boldsymbol{\beta}' = [\beta_1, \beta_2, \ldots \beta_8]$.

Thus, α is the log of the odds that a woman with a "standard" $(\mathbf{x}=0)$ set of independent variables will have a pregnancy which is at risk due to alcohol use. The coefficient β_j measures the change in the log odds for a one unit change in x_j, as

shown by the following equation for a one unit change in x_1:

$$\text{logit } \Pr\{D|x_1+1, x_2 \ldots x_8\} - \text{logit } \Pr\{D|x_1, x_2 \ldots x_8\} = \beta_1.$$

Therefore, the odds ratio (OR) can be expressed as an exponential function:

$$OR = e^{\beta_1}.$$

In addition to estimating the odds of alcohol use by unique sets of patients, a risk odds ratio (ROR) which compares the risk of drinking for two different sets of patients, $\mathbf{x}^*$ and $\mathbf{x}$, can also be calculated.

$$\ln ROR = \text{logit } P(\mathbf{x}^*) - \text{logit } P(\mathbf{x})$$

so that

$$ROR = e^{\boldsymbol{\beta}'(\mathbf{x}^* - \mathbf{x})}.$$

Estimation of Parameters

Using the initial model, estimates of the parameters α and $\beta_1, \beta_2, \ldots, \beta_8$ will be calculated using an unconditional maximum likelihood estimate algorithm. The maximum likelihood function

produces estimates of the parameters which agree most closely with the data actually entered. The use of the unconditional function is appropriate since the number of parameters to be estimated is small relative to the number of individuals in the sample (Kleinbaum, 1982).

Testing the significance of β's

If β_j is equal to zero then the associated x_j is not related to alcohol use since the odds ratio will be equal to one. The null hypothesis, H_{0j}: $\beta_j = 0$ will be tested by the likelihood ratio test, which is based on the ratio of two maximized likelihoods. This ratio provides a χ^2 test statistic of the null hypothesis.

Each of the β's will be tested in turn by calculating the ratio of the likelihood function of the model including all eight independent variables to one in which a single variable has been excluded. The χ^2 statistic which results from that ratio will be used to test the null hypothesis for the β associated with the excluded variable. The test will be considered significant at the .01 level.

Refinement of the initial model

An attempt will be made to refine the regression equation by excluding independent variables which are not significantly related to maternal alcohol use and by adding important two factor

interactions. The forward selection method will be used, starting with the most highly correlated β and sequentially adding factors in order of their previously calculated significance. After each addition the significance of the factor will be calculated using the likelihood ratio test. Once the factors have been added, two factor combinations of significant factors will be added one by one and similarly tested. Interactions will be added in order of the significance of their component factors.

BUDGET

Appendix 9 contains a projection of the resources which will be needed during each phase of the study.

Chapter 3

RESULTS

DATA QUALITY

There are two different types of inaccuracy which may degrade the quality of data. The first, called validity, deals with systematic error. The second, known as precision, is a measure of random error, which is the difference between the estimate of a parameter and the true value of the parameter actually being estimated. It is usually attributable to sampling effects and depends on both sample size and statistical variation. Systematic error occurs when there is a difference between the parameter being estimated and the true parameter which is of interest. It is attributable to bias resulting from errors in design and analysis which are not due to sampling effects.

PRECISION

Prevalance Estimates

Since the prevalence of maternal alcohol use calculated for each clinic is based on a sample of the clinic population, it is an estimate of the true prevalence in the community. The precision of

that estimate is a function of the sample size and of the estimated probability. The precision can be quantitated by the use of confidence intervals for binary outcomes. The 95 percent confidence interval for the true prevalence, p, of drinking in the population is expressed by the formula:

$$p = \hat{p} \pm 1.96\{\hat{p}(1-\hat{p})/n\}^{1/2}$$

where $\hat{p}$ is the estimate of drinking prevalence obtained from the sample and n is the sample size. Confidence intervals for a variety of prevalence estimates and sample sizes are shown in appendix 10.

Regression Estimates

The precision of the estimates of the parameters generated by the maximum likelihood function will also be quantitated. The variation associated with each $\hat{\beta}$ will be used to calculate a confidence interval for that $\hat{\beta}$. If the associated independent variable is related to alcohol consumption, the confidence interval should not include zero. The 95% confidence interval for β_j is:

$$\hat{\beta}_j \pm 1.96\{\mathrm{Var}(\hat{\beta}_j)\}^{1/2}$$

where $\hat{\beta}_j$ is the unconditional maximum likelihood estimate of β_j.

VALIDITY

Complete and accurate data must be obtained from patients or the information which is produced by this study will not be valid. The method of data acquisition has been designed to ensure maximum data quality within the limitations of available resources.

The two most likely sources of bias in this study are selection of subjects and information quality. Selection effects may result from refusal of potential subjects to participate, incomplete questionnaires, or inability to read English.

Selection Bias

PARTICIPATION

Participation in the study will be encouraged through the patient information sheet. The information sheet will inform the patient that the study poses no risk to her, that the data will be kept confidential, and that the results will be of benefit to other pregnant women. While these facts alone should provide very strong motivation to participate, technicians who administer the questionnaire will be instructed to emphasize the importance of participation. Very high participation rates are anticipated.

A participation rate for each clinic will be calculated by dividing the number of patients participating in the study by the

total number of new prenatal patients seen in that clinic during the study period. The participation of patients at each clinic will be compared to the overall participation rate using a χ^2 test of homogenity to evaluate whether participation rates are equal. The hypothesis that all the rates are equal to each other will also be tested. The equal rates hypothesis, $H_0: p_1 = p_2 = \ldots = p_c$, is tested by the chi-square statistic "Q" which has c-1 degrees of freedom.

$$Q = \frac{\sum_{j=1}^{c} n_j (p_j - p)^2}{p(1-p)}$$

Where p is the observed overall participation rate, and the p_j's are the observed participation rates for the various clinics. As before, "p" values will be calculated for all chi-square statistics.

COMPLETION OF QUESTIONNAIRES

The simplicity of the questionnaire, the assurance of confidentiality, and the desire to help other pregnant women should strongly motivate patients to complete all questions. To ensure that the questionnaire is easily understood, it has been simplified to approximately a sixth grade reading level. The type of response has also been simplified to multiple choice where ever possible. Additional quality control will be provided by clinic technicians who will be trained to assist the patient if she needs help. There should be very few incomplete responses. Any patient

whose questionnaire is incomplete or has unusable data will be removed from the study.

LANGUAGE BARRIER

While the questionnaire will only be available in English, this is not expected to be a problem as almost all patients cared for in USAF prenatal clinics are fluent in English. The few dependent wives who are not fluent in English are always accompanied by their husbands who translate for them.

Information Bias

The most likely information bias to be encountered in this study is a distortion of the drinking history. Accuracy of response should be encouraged by the assurance that the data will be confidential and that it will not be used as a basis for individual action. The patient will be able to appreciate that the results will be confidential by the method chosen to have her return the questionnaire. She will be aware that her name does not appear on the questionnaire, and she herself will seal the questionnaire and consent forms in separate envelopes before returning them to clinic personnel.

The accuracy of the self-reported drinking history has been investigated by Russell (1979). Her results indicate that a self-administered questionnaire on prenatal alcohol use will have a

sensitivity of between 65 and 84 percent, and a specificity of 94 to 100 percent. Since her study was of an inner-city population, the results are not necessarily valid for a USAF community. Responses of USAF patients should be at least as accurate, if not more accurate. No attempt will be made to measure the sensitivity or specificity of the questionnaire, because to do this is beyond the scope of this study.

The high specificity reported by Russell indicates that there should be very few non-drinking patients misclassified into the drinking group. The relatively lower sensitivity suggests that a number of prenatal patients who use alcohol will be misclassified as non-drinkers. Therefore, the prevalence of drinking will tend to be under-estimated.

CORRELATION

It is possible that some of the independent variables will be highly correlated. The issue of correlation is important to the understanding of the association of demographic characteristics and drinking behavior. Correlation is a measure of the extent to which one variable can linearly predict another. For example, if ethnic group and socioeconomic status are highly correlated with each other but only ethnicity is associated with alcohol use, both variables will appear to be associated with drinking behavior. It

would be possible to conclude that socioeconomic status was associated with drinking behavior when in fact it was not.

The independent variables will be examined for correlation by calculating correlation coefficients for all 56 possible pairs of variables. Since all variables are dichotomous, the phi (ϕ) coefficient can be used to calculate product-moment correlation coefficients (Kleinbaum, 1982).

$$\phi = (ad-bc)/(mnrs)^{1/2}$$

The notation is the same as that for the two by two table shown on page 24. Variables which are expected to exhibit some degree of correlation are listed below.

1. age, socioeconomic status
2. age, ethnic group
3. age, education level
4. age, parity
5. socioeconomic status, ethnic group
6. socioeconomic status, educational level
7. socioeconomic status, parity
8. ethnic group, educational level
9. ethnic group, parity
10. military status, educational level
11. military status, parity
12. educational level, parity

DISCUSSION

A recently published comparison of health practices of USAF personnel and United States adult civilians has shown that Air Force women report drinking more than their civilian counterparts (Wetzler, 1985). Therefore, it seems reasonable to conclude that prenatal alcohol use among patients attending USAF prenatal clinics will be found to be at least as prevalent as it is among civilians. If this is the case, each year hundreds of alcohol affected children are being born in USAF medical facilities. This study will provide the information necessary to begin to mount an effective attack on this problem.

PREVALENCE

Information regarding prevalence will be available in a number of forms. Use specific rates will be calculated for each clinic as well as the pooled data. These rates are intended to give an overall picture of the prevalence of alcohol use at the different clinics participating in the study. The information on changes in alcohol use in the preceeding year may indicate whether women tend to increase alcohol use at overseas locations or whether there is a trend to decrease consumption prior to conception.

It will also be possible to compare prevalence among the various clinics, and to compare individual clinic use specific rates to

the rates calculated for the pooled data. These comparisons will identify clinics which have the greatest need for maternal alcohol use intervention programs.

RISK FACTORS

Testing the association of individual factors with drinking behavior by chi-squared analysis will indicate which factors are associated with maternal alcohol use. While causation will not be proved, it may be suggested if associations are sufficiently strong. Even in the absence of causal association, risk factor identification will allow high-risk groups to be targeted for the earliest and most intense intervention efforts.

REGRESSION MODEL

The association of prenatal alcohol use to demographic variables through the use of linear logistic regression has not been previously investigated. The linear logistic regression model will precisely quantifiy the relationship between demographic factors and maternal alcohol use. The addition of significant two factor interactions to the model will lead to an understanding of important interrelationships among the variables under study.

Chapter 4

CONCLUSION

ESTABLISHING LOCAL PROGRAMS

This study will provide information which will allow local authorities to determine their need for a maternal alcohol use control program and will also indicate which groups of women should receive the highest priority for that program. Once the need for prenatal alcohol use interventon has been confirmed, it should be a rather straightforward task to establish appropriate intervention programs. This is because all the elements necessary for a multiphasic attack on prenatal alcohol use are already available in all USAF Medical Treatment Facilities. These include health educators, alcohol treatment specialists, preventive medicine physicians, medical administrators, and local disease surveillance programs.

The first step must be the establishment of a uniform policy throughout the USAF which promotes the prevention of prenatal alcohol use. Once this policy has been established, and prevalence and risk factors have been identified, local program planners can effectively mobilize local resources to control prenatal alcohol use.

USAF POLICY CHANGES

In order to achieve Air Force wide screening for maternal alcohol use, a proposal for specific actions will be submitted to the Air Force through its suggestion program. The first part of the suggestion will be to modify the prenatal history form to include at least one question on alcohol use. The form presently in use includes a section which elicits a medical history, but it does not include any questions on alcohol use. The lack of a specific question on the use of alcohol ensures that an alcohol use history is almost never obtained.

The second part of the suggestion will deal with Air Force Regulation 160-12, Professional Policies and Procedures. This regulation should be amended to include a paragraph directing that all prenatal patients are screened for alcohol use during their first prenatal visit. The paragraph should also state that patients identified as alcohol users must be offered counciling and treatment as appropriate, and that local prevention programs will be conducted using existing resources. Those prevention programs should be targeted at women identified locally to be at high risk of alcohol use during pregnancy. The revised regulation should also direct the inclusion of data on maternal alcohol use in the existing disease surveillance program conducted by the Medical Treatment Facility's Medical Intelligence Officer.

SUMMARY

Maternal alcohol use has been found to be a significant public health problem in every prenatal population previously studied. It is almost certainly also a problem in USAF communities and merits immediate attention. This study will indicate whether screening, intervention, and surveillance programs are needed, and which groups of patients will benefit most from them. Prevalence information will give health care providers a measure of the magnitude of the local prenatal alcohol use problem. Risk factor analysis will allow them to concentrate their prevention and intervention efforts on those patients who are at greatest risk to use alcohol during pregnancy. Properly run, these programs can drastically reduce the unnecessary financial and social burden caused by maternal alcohol use.

APPENDIX 1

DIAGNOSTIC SIGNS

I. FETAL ALCOHOL SYNDROME:

A, B, and C must all be present to make the diagnosis of the Fetal Alcohol Syndrome.

A. Prenatal and/or post natal growth retardation with weight, length, and/or head circumference below the tenth percentile

B. Central nervous system involvement with neurological abnormality, developmental delay, or intellectual impairment

C. Facial dysmorphology with at least two of the following three signs:

1. Microcephaly
2. Microphthalmia and/or short palpebral fissures
3. Poorly developed philtrum, thin upper lip, and/or flattening of the maxillary area

II. FETAL ALCOHOL EFFECTS:

Any congenital abnormality seen in children as a result of maternal alcohol use when the full syndrome is not present.

In addition to the malformations listed in paragraph I, the following are also seen in greater than normal frequency:

A. Behavioral disorders

1. attention deficit
2. hyperactivity
3. learning disabilities

APPENDIX 1

B. Fetal Wastage

1. spontaneous abortion
2. stillbirth
3. perinatal death

C. Major and Minor Malformations

1. septal defects
2. labial hypoplasia
3. hemangiomas
4. aberant palmar creases
5. pectus excavatum
6. strabismus and ptosis
7. epicanthal folds
8. cleft lip or cleft palate
9. hirsuitism

APPENDIX 2

PROCESSION PLAN

Stage	Activity	Time Required
Phase I		
step 1	Select facilities to study	15 days
step 2	USAF approval of study	45 days
step 3	Facility commander approval	45 days
sub-total		105 days
Phase II		
step 1	Print forms	5 days
step 2	Mail instructions to clinics	10 days
step 3	Call clinics to confirm participation	5 days
step 4	Mail study materials	10 days
sub-total		30 days
Phase III	Data collection	90 days
Phase IV	Data analysis	30 days
Phase V		
step 1	Preparation of final report	60 days
step 2	Distribution of results	10 days
sub-total		70 days
TOTAL		325 days

APPENDIX 3

QUESTIONNAIRE DESIGN

Section 1: Demographic

1. Name of medical facility: ________________ Air Force Base
2. How old are you? ___ Years old
3. Your (or your husband's) rank: __________
4. Your cultural group: White Black Other
5. Your military status : Active Duty Dependent
6. Did you finish high school? Yes No
7. Where do you live? On-Base Off-Base
8. How many living children do you have? ______

Section 2: Alcohol Use

10. How many times a week do you drink beer? _____
11. About how many cans each time? _____
12. How many times a week do you drink wine? _____
13. About how many glasses each time? _____
14. How many times a week do you drink hard liquor? _____
15. About how many drinks each time? _____
16. Has your drinking changed in the last year? Yes No
17. If it has changed, do you drink more or less? More Less

If you do not want to answer the above questions return this questionnaire and please write your reasons for not wanting to participate in the space below.

APPENDIX 4

INFORMATION FOR PATIENTS

1. The USAF has approved a study of alcohol use during pregnancy at a number of different USAF bases. We are trying to find out how often pregnant women drink alcoholic beverages and what type they drink.

2. We are getting this information by having patients answer a series of questions. These questions are being given to all new patients at this clinic for three months.

3. *The question sheet* will not have any information on it which could identify you. The completed forms will be sent to another base where the answers will be studied. Answers will be absolutely confidential. They will not be used as the basis for any individual actions.

4. If the study is successful we will be able to the improve health care that is given to pregnant women at USAF bases.

5. Your participation in this study is very important. Without your answers to these questions the study will not be complete.

APPENDIX 4

6. Participation is voluntary, and if you don't want to help, just return the question sheet to the person who gave it to you. If you decide not to participate please write the reason in the space provided at the bottom of the questionnaire.

7. If you will be answering the questions, we need to have your written consent. A consent form is attached to the question sheet. Please sign and date it.

8. If you have any questions about how to complete the consent form or the question sheet, ask the person who gave them to you for help.

9. After you answer the questions seal the question sheet in the attached envelope so no one else can read it. Put the consent form and the information sheet in the other envelope, and seal that too. When you have finished, return them to the person who gave them to you.

10. The results of this study will be sent to your clinic in about six months. If you want to know what was found, remember to ask when you are close to your due date.

APPENDIX 5

CONSENT FORM

I, ______________________________ have carefully read the information sheet which explains the study on alcohol use during pregnancy. I understand the purpose of this study, and that my answers to all questions will be kept strictly confidential. I give permission for my answers to be used for statistical purposes only. I understand that my name will never be used in any way in conjunction with this study.

____

Signature   Date

____

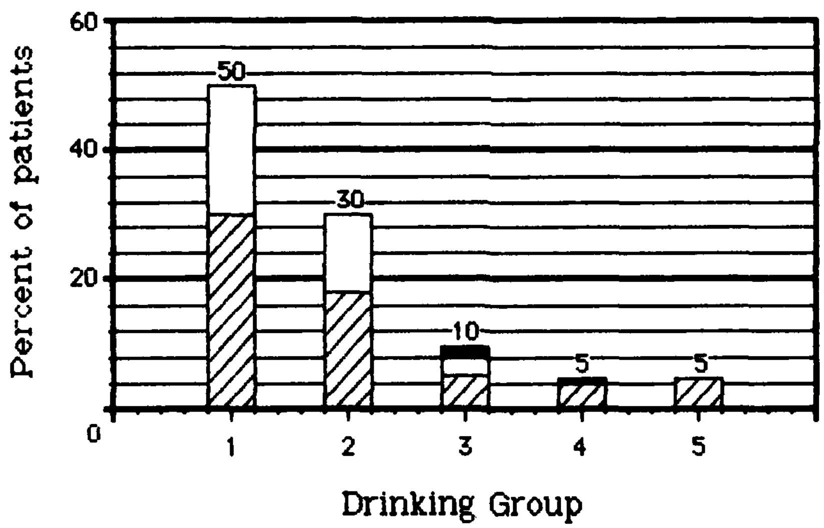
Printed Name

APPENDIX 6

HISTOGRAM OF PREVALENCE DATA

This example demonstrates the design of the histogram depicting prevalence of alcohol use which will be used. The number of women in each drinking category who reported an increase, a decrease, or no change in alcohol use in the past year are depicted. Individual histograms will be plotted for each clinic studied and for data pooled from all clinics.

PREVALENCE OF ALCOHOL USE



KEY

cross hatched area = no change in past year

open area = decrease in past year

filled area = increase in past year

APPENDIX 7

SAMPLE TWO BY TWO TABLE

This table demonstrates the way relationships between individual independent variables and the drinking history will be displayed. A separate table will be constructed for each of the eight demographic variables. The chi-square statistic, "χ^2", and "p" value associated with the variable are also shown.

Variable

Drinking Category	X=0	X=1
D+		
D-		

$\chi^2 =$

p =

APPENDIX 8

INDEPENDENT VARIABLES

variable	description	strata	
		x = 0	x = 1
x_1	Geographic location	CONUS*	Overseas
x_2	Patient's age	≥ 25	<25
x_3	Socioeconomic status	Officer	Enlisted
x_4	Ethnic group	White	Non-white
x_5	Military status	Active duty	Dependent
x_6	Educational level	$\geq 12^{th}$	$<12^{th}$
x_7	Domicile	On-base	Off-base
x_8	Parity	0	>0

* CONUS = Continental United States

APPENDIX 9

BUDGET

Phase	Items	Discription
I	Office Supplies	Misc.
	Postage	Letters to Clinics
	Investigator	40 hours
II	Office Supplies	Paper for printing.
	Printing	800 sheets
	Postage	For study materials
	Investigator	60 hours
III	Administrative Support	360 hrs of Tech. time
	Telephone Calls	To coordinate study
	Postage	Letters to clinics
	Office Supplies	Misc
	Investigator	180 hours
IV	Computer Support	10 hours for statistics
	Biostatistician	4 hours of consultation
	Office Supplies	Misc
	Investigator	100 hours
V	Word Processer	50 hours
	Office Supplies	Misc
	Printing	400 pages
	Postage	To mail results
	Investigator	75 hours

APPENDIX 10

APPROXIMATE 95% CONFIDENCE INTERVALS:
NORMAL APPROXIMATION OF THE BINOMIAL DISTRIBUTION

sample size	observed prevalence					
n	5%	10%	20%	30%	40%	50%
50	0-11	2-18	9-31	17-43	26-54	36-64
60	0-10	2-18	10-30	18-42	28-52	37-63
80	0-10	3-17	11-29	20-40	29-51	39-61
100	1-9	4-16	12-28	21-39	30-50	40-60
150	2-8	5-15	14-26	23-37	32-48	42-58
200	2-8	6-14	14-26	24-36	33-47	43-57
250	2-8	6-14	15-25	24-36	34-46	44-56
500	3-7	7-13	16-24	26-34	36-44	46-54

Confidence intervals calculated using the formula:

$$p = p \pm 1.96\{p(1-p)/n\}^{1/2}$$

LIST OF REFERENCES

Ashley MJ 1981. Alcohol use during pregnancy: a challenge for the '80s. Can Med Assoc J. 125: 141-42

Brown BW and Hollander M 1977. Statistics: A Biomedical Introduction, pp 181-9. New York: John Wiley & Sons

Clarren SK and Smith DW 1978. The fetal alcohol syndrome. N Engl J Med. 298: 1063-67

Eifler CW 1984. Lecture notes in biometry; I and II. University of Texas Health Science Center School of Public Health, San Antonio, TX. (Photocopied)

Food and Drug Administration 1981. Surgeon General's advisory on alcohol and pregnancy. FDA Bull. 11: 9-10

Kleinbaum DG and Kupper LL 1978. Applied Regression Analysis, pp 227-32. North Scituate, MA: Duxbury Press

Kleinbaum DG, Kupper LL, and Morgenstern H 1982. Epidemiologic Research. Belmont, CA: Lifetime Learning Publications

Little RE and Streissguth AP 1981. Effects of alcohol on the fetus: impact and prevention. Can Med Assoc J. 125: 159-164

Lundberg GD 1984. Ethyl alcohol - ancient plague and modern poison. JAMA. 252: 1911-12

Mills JL, Graubard BI, Hartley EE, Rhoads GG, and Berendes HW 1984. Maternal alcohol consumption and birth weight. JAMA. 252: 1875-79

Ouellette EM 1984. The fetal alcohol syndrome. ASDC J Dent Child. 51: 222-24

LIST OF REFERENCES

Rayburn WF and Zuspan FP 1982. Drug Therapy in Obstetrics and Gynecology, pp. 9-12. East Norwalk, CT: Appleton-Century-Crofts.

Rosett HL and Weiner L 1981. Identifying and treating pregnant patients at risk from alcohol. Can Med Assoc J. 125: 149-54

Russell M and Bigler L 1979. Screening for alcohol-related problems in an outpatient obstetric-gynecologic clinic. Am J Obstet Gynecol. 134: 4-12

Segal M, Palsgrove G, Sevy TD, and Collins TE 1983. The 1990 prevention objectives for alcohol and drug misuse: progress report. Public Health Rep. 98: 426-35

Sokol RJ 1981. Alcohol and abnormal outcomes of pregnancy. Can Med Assoc J. 125: 143-48

Streissguth AP, Darby BL, Barr HM, Smith JR, and Martin DC 1983. Comparison of drinking and smoking patterns during pregnancy over a six-year period. Am J Obstet Gynecol. 145: 716-23

Ulleland C, Wennberg RP, Igo RP, and Smith NJ 1970. The offspring of alcoholic mothers. Pediat Res. 4: 474

Warner, RH and Rosett HL 1975. The effects of drinking on offspring. An historical survey of the American and British literature. J Stud Alcohol. 36: 1395-1420

Wetzler HP and Cruess DF 1985. Health practices in United States Air Force personnel compared to United States adult civilians. Aviat Space Environ. Med. 56: 371-5

Wilner DM, Walkley RP, and O'Neill EJ 1978. Introduction to Public Health, p. 222. New York, NY: Macmillan

VITA

Howard Gillis II was born to Howard and Rosanne Gillis in Chicago, Illinois, on the 19th of February, 1946. After graduating from New Trier High School, Winnetka, Illinois, he attended the Massachusetts Institute of Technology, where he was elected to Phi Lambda Upsilon, the national honorary chemistry society. In 1967 MIT awarded him the Bachelor of Science degree with a major in life sciences. He then attended Northwestern University Medical School where he was elected to the national honorary medical society, Alpha Omega Alpha, in 1970. The following year he graduated with distinction, receiving the degree of Doctor of Medicine.

After graduation from medical school he received four years of post-graduate training in Obstetrics and Gynecology at the Milton S. Hershey Medical Center of the Penn State University. Following completion of this specialty training he entered the USAF, where after additional medical training he was awarded the aeronautical rating of flight surgeon. In 1976 he was certified by the American Board of Obstetrics and Gynecology, and soon thereafter was elected a Fellow of the American College of Obstetrics and Gynecology.

After a two year assignment to the USAF Hospital at George AFB in California, where he served first as chief of the obstetrics and gynecology service, and later as chief of aeromedical services, he was transfered to the USAF Clinic at RAF Bentwaters, England. Dr Gillis was assigned to Bentwaters for a total of seven and one-half years where he served first as a flight surgeon, and later as chief of aeromedical services. In 1983 he was awarded the aeronautical rating of senior fight surgeon.

He is married to Jennifer Anne Roscoe of Philadelphia. They have four children: ages 18, 17, 13, and 11 years.

Permanent address: 7226 Castor Avenue
Philadelphia, PA 19149

END

FILMED

12-85

DTIC